

REMARKS

Claims 1, 7, 19, 20, 27, and 38-40 are pending in the present application. Applicants respectfully request entry and consideration of the present Response, at least for the purpose of putting the present application in better condition for appeal. No amendments that would require an additional search are included.

Claims 1, 7, 19, 20, 27, and 38 have been rejected under 35 U.S.C. §103(a) as being unpatentable over United States Patent No. 6,559,189, to Baker, Jr. et al., ("Baker") in view of United States Patent No. 6,335,012, to Fischetti et al. ("Fischetti") Claims 1 and 20 are independent. Applicants respectfully traverse.

Claim 1 is directed to a tampon comprising an absorbent material and a composition disposed in the absorbent material. The composition comprises at least one antibacterial agent in an amount of about 0.10 wt% to about 2.5 wt% of the total weight of the tampon, and at least one finishing agent in an amount of about 2.5 wt% of the total weight of the tampon. The antibacterial agent is a mixture of alkyl dimethyl benzylammonium chloride and alkyl dimethyl ethylbenzylammonium chloride. The at least one finishing agent is one or more polyoxyethylene fatty acid esters. The composition has synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin and reduce Staphylococcus aureus bacteria growth.

The Final Action states on p. 2 that "the claimed range for the antibacterial agent remains broader than the amounts shown in Table 1 to provide a reduction in bacterial growth." Applicants respectfully submit that this statement misses the fact that the claimed amount of finishing agent is clearly shown to be critical, and that is enough to establish the patentability of claim 1.

As shown in Table 1 of the present specification, the two samples with 2.5% of the finishing agent, Tween 20, exhibit vastly improved TSST-1 reduction when compared to the two samples with 0.25% of Tween 20. This is true whether the

concentration of the antibacterial agent BTC 2125M is 0.25%, or 1.0%. The data concerning the samples having the claimed about 2.5% of finishing agent thus establish the criticality of this amount, even at different amounts of antibacterial agent, over the 0.5 - 2% of Tween 20, based on the weight of the composition, that is disclosed in Baker. Therefore, claim 1 is patentable over the combination of Baker and Fischetti, as are claims 7, 19, and 39, which depend therefrom.

Claim 7 depends from claim 1, and further recites that the at least one antibacterial agent is present in an amount of about 1.0 wt.% based on the total weight of the tampon. As shown in Table 1, the embodiment having 1.0% of BTC 2125M and 2.5% of Tween 20 exhibits vastly improved TSST-1 reduction over embodiments outside of these ranges. Furthermore, the embodiment having 1.0% of BTC 2125M and 2.5% of Tween 20 also exhibits vastly improved *S. aureus* reduction when compared to the control and other embodiments of the present disclosure. Thus, the amounts of antibacterial agent and finishing agent recited in claim 7 establish further criticality over what is disclosed in Baker, namely 0.5 - 2% of Tween 60, based on the weight of the composition, and 0.5 - 2% of quaternary ammonium compound, based on the weight of the composition. This additional criticality is further support of the patentability of claim 7.

Claim 20 recites a method of inhibiting the production of TSST-1 toxin by exposing TSST-1 toxin-producing *Staphylococcus aureus* bacteria to a tampon. The tampon comprises an absorbent material and a composition. The composition has, *inter alia*, at least one antibacterial agent in an amount of about 0.10 wt% to about 2.5 wt%, and at least one finishing agent in an amount of about 2.5 wt%, each based on the total weight of the tampon.

As previously discussed with respect to claim 1, the data in Table 1 establishes the criticality of the claimed amount of finishing agent over what is disclosed in the combination of Baker and Fischetti. Therefore, claim 20 is patentable over Baker in view of Fischetti under 35 U.S.C. §103(a), as are claims 27, 38, and 40, which depend

therefrom.

Claim 27 depends from claim 20, and recites that the at least one antibacterial agent is present in an amount about 1.0 wt% based on the total weight of the tampon. As discussed above with respect to claim 7, Table 1 establishes the criticality of the claimed amounts of antibacterial agent and finishing agent, and this is further support of the patentability of claim 27.

Claims 39 and 40 depend from claims 1 and 20, respectively, and recite that the claimed compositions consist essentially of the recited components. The Final Action cites the embodiment of Baker disclosed at col. 5, l. 13-19. Applicants respectfully submit that Baker recites that the cited embodiment discloses "a first component comprising an alcohol or glycerol, and a second component comprising a surfactant or a halogen-containing compound" (emphasis added). This is contrary to the Final Action's statement that the cited embodiment discloses "the oil-in-water emulsion, a surfactant, and a halogen-containing antibacterial compound."

In addition, the Final Action states that absent a showing that the oil-in-water emulsion would materially affect the claimed invention, the "consisting essentially of" transitional language of claims 39 and 40 will include the oil-in-water emulsions of Baker. Applicants respectfully disagree.

As stated in the MPEP, the transitional phrase "consisting essentially of" excludes any features that materially affect the basic and novel characteristics of the claimed invention. §2111.03. Baker states that the oil-in-water emulsion comprising the oil phase alcohol solvent is used for "decreasing the infectivity of microorganisms." (col. 4, l. 37-39) The solvents are beneficial because they "disrupt the lipids in the membranes of the pathogens." (col. 15, l. 47-48) Therefore, oil phase solvents would clearly affect the basic and novel characteristics of the claimed compositions, in that they would decrease "infectivity" of microorganisms. Consequently, these oil phase solvents would be excluded by the "consisting essentially of" language of claims 39 and

40. This is further support of the patentability of these claims.

Applicants respectfully submit that the rejection of claims 1, 7, 19, 20, 27, and 38-40 under 35 U.S.C. §103(a) as being unpatentable over Baker in view of Fischetti has been overcome. Applicants respectfully request that it be withdrawn.

Therefore, Applicants respectfully submit that the present application is in condition for allowance. The issuance of a Notice of Allowance is earnestly solicited.

Respectfully submitted,

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/Michael S. Bartolone/
Michael S. Bartolone
Reg. No. 65,239
Attorney for Applicants
Ohlandt, Greeley, Ruggiero & Perle, L.L.P.
One Landmark Square, 10th floor
Stamford, CT 06901-2682
Tel: (203) 327-4500